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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,861

03/21/2005

Kenichiro Kosai

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EXAMINER

LEAVITT, MARIA GOMEZ

ART UNIT

PAPER NUMBER

1633

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

02/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/518,861

Applicant(s)

KOSAI ET AL.

Examiner

Maria Leavitt

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. Claims 1-23, 33-36, and 24-29 drawn to a first vector comprising a first recombinant DNA, a second vector comprising a second recombinant DNA, an embryonic stem cell transformed with said first and second vectors, a tissue comprising said cell[AW1], method for selectively isolating or visualizing a target cell differentiated from said embryonic cell and a kit comprising said vectors and said embryonic stem cells.

II. Claim 37-38 drawn to a method for treating a disease with an embryonic stem cell transformed with said first and second vectors.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

37 CFR 1.475 (c) states:

“If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present”

37 CFR 1.475 (d) also states:

“If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each

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of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)".

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons: the technical feature linking Groups I-II appears to be that they all relate to a method for isolating or visualizing a target cell differentiated from embryonic cells after transfection with a first and second recombinant DNA, wherein differentiation induces activation of a second promoter in the second transfected DNA inducing expression of recombinant Cre which itself induces expression of a marker gene encoded by the first recombinant DNA. However, prior art has described efficient systems for conditional gene expression in embryonic stem cells that rely on tamoxifen-dependent Cre recombinase-loxP site-mediated recombination and two bicistronic gene-trap expression vectors that allow transgene expression from endogenous cellular promoters (Vallier et al., PNAS 2001, 2467-2472). Therefore, the technical feature linking the invention of groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over prior art for the reasons set forth above.

This application contains claims directed to more than one species of the generic invention. Generic claims will be examined as they correspond to the selected groups. Currently claims 1 and 37 are generic, for example. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PTC Rule 13.1

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Species Restriction.

Should Groups I be elected, a species restriction is further required under 35 U.S.C. 121 and 372, **wherein a species election(s) must correspond to an elected group as indicated above.**

This application contains claims directed to the following patentably distinct species:
CMV promoter, CA promoter

1) Applicant is required to choose one specifically named constitutively strong expression promoter as recited in **claim 4.**

The species are independent or distinct because there are methods comprising promoter genes having different chemical structures, physical properties, and biological functions as a result of containing different expressed genes or chemical compounds (e.g., CMV is a cytomegalovirus cytomegalovirus early gene enhancer promoter, CA is a hybrid promoter of cytomegalovirus enhancer and chicken β actin promoter)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 37 are generic.

This application contains claims directed to the following patentably distinct species:
a Nkx2.5 gene promoter, α MHC promoter.

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2) Applicant is required to choose one specifically named promoter specifically expressed only in a differentiating target cell as recited in **claim 7**.

The species are independent or distinct because there are methods comprising promoter genes having different chemical structures, physical properties, and biological functions as a result of containing different expressed genes or chemical compounds (e.g., Nkx2.5 a gene which is specifically expressed only in a differentiating target cell; α MHC a cardiac myosin heavy chain)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 37 are generic.

This application contains claims directed to the following patentably distinct species: neuronal cells, striatal cells, parental cells or cells expressing huntingtin.

The species are independent or distinct because there are cellular systems comprising cells with genes having different physical properties and biological functions (e.g., transmission of nervous stimulus, myeloma cells).

2) Applicant is required to choose one specifically named cellular system as recited in claims 8, **9 and 10**.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 37 are generic.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding his application should be directed to Group Art Unit 1636; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

ANNE M. WEHBE PH.D
PRIMARY EXAMINER



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